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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,752	08/07/2001	Maneesh Jain	2002850-0015	3181

24280 7590 12/16/2005

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,752	JAIN ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-13,15-67 and 113-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-13,15-23,26-36,38-41,43-59,61-63,65-67 and 113-124* is/are rejected.

7)☒ Claim(s) *24,25,37,42,60 and 64* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on September 6, 2005 has been acknowledged and entered.

Claims 1-5, 7-13, 15-67 and new claims 113-124 are pending.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph is withdrawn herein.

Rejection under 102 by Zhou is withdrawn herein.

Rejection under 103 by Zhou is withdrawn herein.

Claim Objections

Claims 7-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 4. See MPEP § 608.01(n). Accordingly, the claims 7-9 not been further treated on the merits.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,

> except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-10, 12, 15, 21-23, 26-30, 32, 35-36, 38-41, 59, 61-63, 65-67, 114-118 are rejected under 35 U.S.C. 102(e) as being anticipated by Baglin et al.(US 6,440,520).

Baglin teaches a disk substrate with patterned magnetic regions that are raised above the surface substrate. (see col. 2, lines 36-37; fig. 1). Regarding the limitation in claim 1 that the magnetic regions produce a plurality of localized magnetic fields when magnetized and the localized magnetic field are sufficient to trap a magnetic particle with trapping energy of at least five times greater than the thermal energy of the particle at room temperature, these are functional limitations, and the substrate of Baglin is the same as the substrate of claim 1 and thus would function like the claimed device. Claims 2-5 are rejected because they depend from these functional limitations. The magnetic regions have walls that are perpendicular to the substrate (see fig. 1). The magnetic material regions are arranged in a patterned of mutually perpendicular rows and columns. (see fig. 1). The magnetic regions comprise a layer of magnetic material (magnetic layer 24 of fig. 4) and a layer of non-magnetic material (ref. 22 of fig. 4) wherein the layer of non-magnetic material is located between the substrate (ref. 20 of fig. 4) and the layer of magnetic material (see fig. 4).The magnetic regions are uniform in shape and size. The magnetic regions have a circular cross-section. (see fig. 1). The elevated features of magnetic regions are 1 um in diameter at the base and 1 um apart.

The spacing is varied from 1 to 10 um. The substrate is silicon which is non-magnetic (see co. 3, line 63-col. 4, line 9). Regarding claims 22, 23, 26, 39-41 wherein the magnetic particles are further limited, these claims are rejected because they depend from the functional limitations of claim 1. Regarding claim 38, wherein the magnetic regions are formed by photolithography, which is a product by process claim. Thus, no patentable weight is given to the process limitations because regardless how the magnetic particles are made, the structure of the magnetic region is not altered by the device as claimed.

Claims 1-5, 10-12, 15, 21-23, 26, 30, 31, 33, 34, 35, 38-41, 45, 46, 48, 49, 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Gombinsky et al. (US 5,395,498).

Gombinsky teaches a magnetic particle matrix (support layer) which can be formed on a planar substrate which can be a sheet capable of adsorbing the particles, such as a nitrocellulose sheet, paramagnetic sheet, cellulose acetate sheet, zerographic paper. The matrix can be prepared on a rigid substance such as a glass, a flat iron plate or an inert plastic substance, in which case the particles can be immobilized onto said rigid substance by means of a magnet attached at its other side. The (see 3, lines 54-62). The particles are evenly distributed in the matrix or non-uniformly distributed, for examples concentrated in specific locations of the matrix. Magnets arranged in a desired pattern (magnetic layer) can be used to immobilize magnetic particles to the matrix. The magnetic regions comprise a magnetic material which is a superparamagnetic material. The magnetic particles are uniform in size and shape and

are superparamagnetic or ferromagnetic. (see col. 3, lines 1-10). The molecules are DNA, antibodies etc. (see 7, lines 35-40). The matrix can be incorporated into a gel (modified with a polymer). The magnetic particles having a diameter in the range of 100 to 1500nm. (see col. 7, lines 40-45). The pattern of spots in the array is simple rows of lines. (see fig. 2a). The magnetic particles have a core made of a magnetic substance such as ferrous oxide and optionally having a coating which confer the particles binding specificity. Suitable particles have affinity to a different specific species of biological macromolecules. (see col. 7, lines 50-55). Regarding the limitation in claim 1 that the magnetic regions produce a plurality of localized magnetic fields when magnetized and the localized magnetic field are sufficient to trap a magnetic particle with trapping energy of at least five times greater than the thermal energy of the particle at room temperature, these are functional limitations, and the substrate of Gombinsky is the same as the substrate of claim 1 and thus would function like the claimed device. Claims 2-6 are rejected because they depend from these functional limitations. Regarding claims 22, 23, 26, 39-41 wherein the magnetic particles are further limited, these claims are rejected because they depend from the functional limitations of claim 1. Regarding claim 38, wherein the magnetic regions are formed by photolithography, which is a product by process claim. Thus, no patentable weight is given to the process limitations because regardless how the magnetic particles are made, the structure of the magnetic region is not altered by the device as claimed.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 122 is rejected under 35 U.S.C. 102(e) as being anticipated by Baglin (US 6,331,364).

Baglin teaches a device comprising a substrate having a plurality of magnetic regions, wherein the magnetic regions produce a plurality of magnetic fields when magnetized, and the magnetic regions are cobalt. (see col. 2, line 65-col. 3, line 11). Since the magnetic regions of Baglin comprises cobalt, they can trap magnetic particles with a trapping energy at least five times greater than the thermal energy of the particle at room temperature.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 123 is rejected under 35 U.S.C. 102(b) as being anticipated by Andresen (US 4,397,560).

Andresen teaches a photometer for sensing the optical density of a plurality of liquids coated in a microtray provided with a rectilinear array of wells is provided with a device for locating each well in alignment with the photodetectors and a plurality of

magnets associated with the microtray and a plurality of magnet sensors associated with the photodetector to provide signals indicative of the specific well in alignment with the photodetector. (see abstract). The plurality of magnets aligning each well is the magnetic region and photodetectors. Since Andresen teaches his device comprises a plurality of magnetic regions and a plurality of photodetectors, such device can perform functional limitations such as trapping the magnetic particles so as to detect an optical signal from the trapped magnetic particles; or when localized the magnetic fields are sufficient to trap a magnetic particle with a trapping energy at least five times greater than the thermal energy of the particle at room temperature.

Claim 124 is rejected under 35 U.S.C. 102(e) as being anticipated by Blankenstein.

Blankenstein teaches a micro flow system for separating magnetic particles; the system comprises of flow channels with a serial array of assay sites and permanent magnets positioned to separate cartridge. (see fig 13, col. 19, lines 60-67). Since Blankenstein teaches his device comprises a plurality of magnetic regions and a plurality of photodetectors, such device can perform functional limitations such as trapping the magnetic particles so as to detect an optical signal from the trapped magnetic particles; or when localized the magnetic fields are sufficient to trap a magnetic particle with a trapping energy at least five times greater than the thermal energy of the particle at room temperature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baglin or Gombinsky.

Baglin or Gombinsky have been discussed above.

However, Baglin or Gombinsky fail to teach the number of magnetic regions is at least 1000, 10,000, 100,000, 250, 000, or 1,000,000 per centimeter squared.

Baglin or Gombinsky disclose the claimed invention. It would have been obvious to one having ordinary skill in the art at the time the invention was made to arrive at the number of magnetic regions, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2 272, 205 USPQ 215 (CCPA 1980).

Claims 113, 119-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baglin or Gombinsky.

Baglin and Gombinsky have been discussed above.

However, Baglin and Gombinsky fail to teach that the size and shape and spacing of the magnetic regions are selected to increase the likelihood of trapping only a single magnetic particle within the gaps; the magnetic regions have a maximum

length that is between 3 and 5 times as great as the maximum width or between 5 to 10 times as great as the maximum width; the distance between the ends of adjacent magnetic regions in the dimension of the maximum length is 200 microns or less.

Baglin and Gombinsky teach the claimed invention except for the limitations of claims 113, 120 and 121. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the magnetic regions having a maximum length that is between 3 to 5 times as great as the maximum width or between 5 to 10 times as great as the maximum width; and the distance between the ends of adjacent magnetic regions in the dimension of the maximum length is 200 microns or less, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F2d. 272, 205 USPQ 215 (CCPA 1980). Regarding claim 119, since Baglin and Gombinsky teaches the same device as that of the present invention, such device of Baglin or Gombinsky can be used to trap a single bead within the gap, it is within one of ordinary skills in the art to selected the size , shape and spacing of the magnetic regions to trap a single magnetic bead within the gaps

Claims 47, 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinsky in view of Zhou (US 6,355,491).

Gombinsky has been discussed above.

However, Gombinsky fails to teach that the magnetic particles are paramagnetic beads; comprise a detectable moiety which is fluorescent or luminescent molecule; the detectable moiety comprises a nucleic acid which comprises a hybridization tag.

Zhou teaches electromagnetic chips and electromagnetic biochips having arrays of individually addressable micro-electromagnetic unit chip with ligand molecules immobilized on its surface. The chip comprises a plurality of micro-electromagnetic units (magnetic regions) fabricated on a substrate, which can be made of silicon, glass, silicon-oxide, plastics, ceramics or other solid or porous materials. The magnetic regions project above the surface of the substrate and have walls that are substantially perpendicular to the substrate (see fig. 1). The ligand molecules are linked to magnetic beads and together are immobilized on the biochip by the magnetic field generated by energized magnetic units which exert magnetic forces on the magnetic beads and bring the overall molecular assembly into contact with the surface of the biochip above the energized electromagnetic unit. (see col. 17, lines 5-62; figure 1; col. 18, lines 6-51). The different molecules can be DNA, biological receptors. (see col. 7, lines 54-61; col. 19, lines 15-40). The magnetic layer comprises of a sheet of plastic material impregnated with a ferromagnetic material (see col. 9, line 65-col. 10, line 13). There is a first layer of conductive traces on the substrate running between the columns of ferromagnetic cores; a first insulation layer of conductive traces on the surface of the first insulation running between the rows of ferromagnetic cores, perpendicular to the first conductive traces; a second insulation layer on the chip surface that covers the ferromagnetic core array and the second layer of conductive traces (see col. 6, lines 40-52). The superparamagnetic/ paramagnetic microbeads may range in size from less than 100 nm to more than 100 um. These magnetic particles are uniform in size and shape and are trapped by the localized magnetic fields and comprise a detectable

moiety such as a fluorescent, luminescent, nucleic acid, hybridization tag, and have a probe attached thereto. (see col. 19, lines 15-65). The pattern of magnetic regions in the array is organized rows and columns (see fig. 1). The magnetic regions are arranged in an array of subarrays configurations; and are uniform in shape and size, rectangular shape. (fig. 1).

It would have been obvious to one of ordinary skills in the art to use paramagnetic beads which comprises a detectable moiety such as a luminescent or fluorescent or a nucleic acid comprising a hybridization tag as taught by Zhou in the device of Gombinsky because both references teach planar arrays comprising of magnetic regions separated by non-magnetic gaps. Having detectable moieties attached to magnetic beads are convenient in assay for separation and detection simultaneously. Magnetic beads are used for separation unbounds from bounds, and detectable moieties are used to detect the target molecules separated by the magnetic beads.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinsky in view of Andresen.

Gombinsky and Andresen have been discussed above.

However, both fail to teach the device further comprises of a plurality of photodetectors located in locations for trapping the magnetic fields so as to detect an optical signal from trapped particles.

Andresen teaches using photodetectors in conjunction with the magnetic regions.

It would have been obvious to one of ordinary skills in the art to add photodetectors as taught by Andresen to the magnetic array of Gombinsky for detection of magnetic particles since both teach using magnetic regions.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinsky in view of Blankenstein.

Gombinsky has been discussed above.

However, Gombinsky fails to teach a microfluidic assembly comprising channels positioned so as to allow introduction of fluids to the magnetic regions.

Blankenstein has been discussed above.

It would have been obvious to one of ordinary skills in the to arrange an assembly of channels as taught by Blankenstein in the substrate array of Gombinsky so that magnetic particles can flow through the magnetic regions via the channels and such assembly enables detection of sample in fluids or separation of fluid sample to capture the magnetic particles.

Response to Arguments

Applicant's arguments filed September 06, 2005 have been fully considered but they are not persuasive.

Regarding the 102 rejection by Baglin, Applicants argue that Baglin fails to teach the newly added limitation which recites that the magnetic regions have gaps between them and have a maximum length and a maximum width, with the maximum length is greater than the maximum width, and wherein the magnetic regions produce a plurality of localized magnetic fields when magnetized and the are sufficient to trap a magnetic

particle between the magnetic regions. Applicants also submit that the magnetic regions of Baglin have a circular cross-section and therefore do not have a maximum length and width with the maximum length being greater than the width. Furthermore, since the magnetic regions of Baglin are symmetric about their axis, one of ordinary skills in the art would immediately recognize that the regions of Baglin would not produce forces that would trap a magnetic particle between the regions as recited in claim 1.

Baglin teaches that the elevated features of the magnetic regions are 1 um in diameter at the base and 1 um apart. (col. 3, lines 38-39). The diameter at the base which is the maximum diameter is equivalent to the maximum width as claimed in the present invention. Baglin also teaches that the elevated features or holes are irregular in shape. (see col. 3,line 66). Thus, the shape is not rectangular. Also, figure 1 shows that the elevated features or magnetic regions are in the shape of a cone with the maximum width as the diameter (at the base) and the maximum length is the axis of the cone which is greater than the maximum width or the maximum diameter of the holes/elevated features/magnetic regions. Regarding the argument that the regions of Baglin would not produce forces that would trap a magnetic particle between the regions as recited in claim 1, since the magnetic regions of Baglin is the same as that of the present invention, it would produce forces that would trap a magnetic particle between the regions as claimed.

Regarding claim 5, since the magnetic regions of Baglin is the same as that of those claimed, they would have north and south poles that produce a plurality of localized magnetic fields when magnetized and wherein the regions are appropriately

shaped and sized so as to generate localized magnetic fields that exist substantially in a volume between the adjacent north and south poles of adjacent magnetic regions above and parallel to the upper surface of the device and wherein the magnetic fields are sufficient to trap a magnetic particle with a trapping energy at least three times greater than the thermal energy of the particle at room temperature. Baglin's device has an upper surface- see fig. 2, the protective layer 16.

Regarding claim 59, since the array of Baglin is positioned in columns and rows, and the claimed array are also arranged in columns and rows, the magnetic regions of Baglin are also spaced apart along the dimension of the maximum width and along the dimension of the maximum length and the distance separating adjacent regions in the dimension of the length is less than the distance separating adjacent regions of the dimension of the width.

Regarding the 102 rejection by Gombinsky, Applicants argue that Gombinsky does not teach a device comprising a plurality of magnetic regions having gaps between them, wherein the magnetic regions produce a plurality of localized magnetic fields when magnetized, and wherein the localized magnetic fields are sufficient to trap a magnetic particle between the magnetic regions as recited in claim 1. Gombinsky teaches arrangements comprising a plurality of magnets and that such magnets can be used to either prepare a matrix comprising magnetic particles or to facilitate the collection of magnetic particles from a matrix. However, the embodiments of Gombinsky do not capture magnetic particles in gaps between the magnets as in amended claim 1 but rather above the magnetic layer, either in a gel above the magnets or on a net

above the magnets. Furthermore, in the arrangement taught in example 1 of Gombinsky, the magnets are separated by rubber strips rather than by gaps as in claim 1. The instant application clearly indicates that gap must be able to accommodate bead and thus cannot be filled with rubber. In the arrangement of example III in Gombinsky, there are only two magnetic regions, since the magnets are placed in two pairs, which would be insufficient to produce a "plurality" of localized magnetic fields.

Gombinsky, in example, teaches that eight flat square fine tin-coated magnets, 20 mm each side and 4 mm thick were attached to pairs to give 4 mm rectangles. Each of the 4 rectangles was separated from each other by 40 mm X 20 mm X 2 mm rubber sheets, to form alternating layers of magnets and rubbers. Thus, the magnetic layers are in strips and are rectangular with width and length. The gaps are the rubber layers. Since Gombinsky's planar array with magnetic regions separated by gaps and is the same as the array of the claimed invention in claim 1, Gombinsky's array is able to produce a plurality of localized magnetic fields when magnetized and these magnetic fields can trap a magnetic particle between the magnetic regions.

Regarding claim 5, since the magnetic regions of Gombinsky is the same as that of those claimed, they would have north and south poles that produce a plurality of localized magnetic fields when magnetized and wherein the regions are appropriately shaped and sized so as to generate localized magnetic fields that exist substantially in a volume between the adjacent north and south poles of adjacent magnetic regions above and parallel to the upper surface of the device and wherein the magnetic fields are sufficient to trap a magnetic particle with a trapping energy at least three times greater

than the thermal energy of the particle at room temperature. Gombinsky's device has an upper surface- see fig. 2b, character 5.

Regarding claim 3, since the array of Gombinsky is positioned in columns and rows, and the claimed array are also arranged in columns and rows, the magnetic regions of Gombinsky are also spaced apart along the dimension of the maximum width and along the dimension of the maximum length and the distance separating adjacent regions in the dimension of the length is less than the distance separating adjacent regions of the dimension of the width.

Allowable Subject Matter

Claims 24, 25, 37, 42, 60, 64 are free of prior arts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
November 22, 2005

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12/12/05